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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,597	02/04/2004	James D. Ralph	SPINE 3.0-447 CONT	3441
51640	7590	10/20/2006	EXAMINER	
SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			HOFFMAN, MARY C	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/771,597

Applicant(s)

RALPH ET AL.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/4/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/13/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by McKeever (U.S. Patent No. 801,151).

McKeever disclose an instrument capable of holding an intervertebral spacer, the instrument comprising a shaft having a proximal end forming a handle (ref. #3), and a distal end forming a claw subassembly. The claw subassembly including a first pincer (ref. #2) fixed at the distal end of the shaft and a second pincer (ref. #9) which is capable of being selectively rotated into and out of a holding association with the first pincer capable of holding and releasing, respectively, a spacer. The instrument further comprises an actuation mechanism for selectively rotating the second pincer. The second pincer is rotateably mounted to the shaft and is spring biased away from the first pincer (ref. #14). The first and second pincers have opposing curved outer surfaces that extend to the distal end of the instrument. The actuation mechanism comprises a sliding member (ref. #16) mounted to the shaft which is selectively moveable in the distal direction by a force sufficient to overcome the bias of the spring, the distally directed movement of the sliding member capable of causing the second pincer to move toward

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the fixed first pincer, and the subsequent reaction of the sliding member in a proximal direction causes the sliding member to disengage the second pincer and the permit the pincers to separate under the bias of the spring. The second pincer includes a tapered surface, which is engaged by a corresponding surface of the sliding member, the engagement causes the second pincer to rotate relative to the first pincer. The pair of pincers, a first being fixed, and a second being coupled to the first in open-biased opposition; and a sliding element capable of translating into and out of engagement with the second pincer to close and opening the pair of pincers. The pair of pincers defines an intervertebral spacer grasping enclosure having an access opening. An intervertebral spacer is capable of being passed for placement into the enclosure when the sliding element is out of engagement, and the spacer is capable of being securely maintained between the first and second pincers when the sliding element has been translated into engagement with the second pincer. The first and second pincers are mounted at the distal end of a common shaft, and the sliding element is capable of being translated along the shaft; and wherein the second pincer has a portion thereof which is engaged by the sliding element to close the pair of pincers. The second pincer is mounted to the common shaft by a pivot joint (ref. #10), and the portion of the second pincer which is engaged by the sliding element is a tapered surface, the angle of which tapered surface, when engaged by the sliding element, is capable of causing the second pincer to rotate about the pivot joint, closing the first and second pincers.

With regard to the statement of intended use and other functional statements, e.g. "a sliding element which may be selectively translated....said pair of pincers,

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respectively" in claim 6, they do not impose any structural limitations on the claims distinguishable over McKeever, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller (U.S. Patent No. 5,122,130).

Keller discloses an instrument capable of holding an intervertebral spacer, the instrument comprising a shaft having a proximal end forming a handle (ref. #13), and a distal end forming a claw subassembly. The claw subassembly including a first pincer (ref. #10) fixed at the distal end of the shaft and a second pincer (ref. #11) which is capable of being selectively rotated into and out of a holding association with the first pincer capable of holding and releasing, respectively, a spacer (ref. #3). The instrument further comprises an actuation mechanism for selectively rotating the second pincer. The first and second pincers have opposing curved surfaces (outer curved surfaces) that extend to the distal end (end region) of the instrument. The spacer has a groove

defining a central core (see FIG. 1) and a pair of flange portions at opposing ends. The spacer is cylindrical and the groove is annular.

### ***Response to Arguments***

Applicant's arguments filed 07/20/2006 have been fully considered but they are not persuasive.

Applicant contends that the device of McKeever does not have curved opposing surfaces. The examiner respectfully disagrees, since Applicant has not specifically claimed inner curved surfaces, the outer surfaces of the pincers can be considered the "opposing curved surfaces that extend to a distal end of said instrument".

Also, Applicant believes that claim 6 has been amended to overcome the McKeever reference. The examiner respectfully disagrees. The source of this disagreement appears to be due to the interpretation of the functional language "a sliding element which may be selectively translated....said pair of pincers, respectively" in claim 6. The term "may be" is broad, and it is being interpreted as used to express possibility. It is possible that the McKeever reference functions in the way claimed by Applicant. Also, it appears that the slider denoted by ref. #16 is capable of sliding all the way down the shaft towards ref. #3, and therefore, the slider would not be in contact with the second pincer. When the slider is moved up the shaft toward ref. #5, the slider will contact the second pincer causing the second pincer to rotate towards the first pincer, thereby meeting the functional language requirement.

Applicant's amendments to claim 5 have necessitated the new ground(s) of rejection presented in this Office action.

***Conclusion***

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

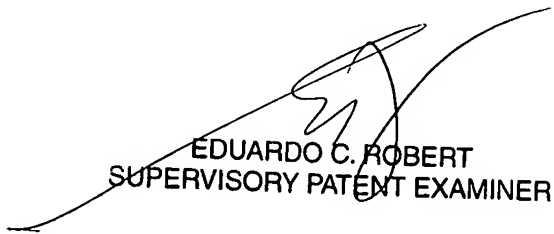
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER